QMS Procedure Manual

ISO 9001:2015

Kentmaster Equipment (Aust) Pty Ltd

Unit 2, 24 Central Court, Browns Plains, Qld 4118

Certificate No: AU 1581

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M01 - Scope of Quality Management System

Introduction

This scope has been produced in line with the requirements of the latest quality management system standard ISO 9001:2015 Clause 4.3. We will ensure that it is made available to all interested parties.

The scope details the types of products and services covered and justification for any requirements not covered by the scope.

Scope of our Management System

Kentmaster Equipment (Aust) Pty Ltd specialises in the manufacture and supply of quality tool, equipment and consumable products for the meat packing industry to the Australian and South East Asian Markets.

Our operations do not utilise any equipment requiring Calibration consequently this element of the Standard has been excluded.

Additionally, we do not engage in any form of Design and Development activity as this is all undertaken from our United States company.

At Kentmaster Australia we supply and service Pneumatic and Hand held stunners to abattoirs that came under the banner of ESCAS to ensure good Animal Welfare practices. This also allows for good working relationships and co-operation to be formed with the main Australian exporters (Wellard, SEALS, AUSTREX, ILE, Frontier, NACC, Hallen) of live cattle, sheep and goats to all overseas markets.

This has also allowed Kentmaster to promote safe working conditions as well as improved food safety with the use of our Vac San Carcass sanitation system.

M02 - Quality Policy

We have established this quality policy to be consistent with the purpose and context of our organization. It provides a framework for the setting and review of objectives in addition to our commitment to satisfy applicable customers', regulatory and legislative requirements as well as our commitment to continually improve our management system.

Customer focus: As an organization we have made a commitment to understand our current and future customers' needs; meet their requirements and strive to exceed their expectations.

Leadership: Our Top Management have committed to creating and maintaining a working environment in which people become fully involved in achieving our objectives.

Engagement of people: As an organization we recognise that people are the essence of any good business and that their full involvement enables their abilities to be used for our benefit.

Process approach: As an organization we understand that a desired result is achieved more efficiently when activities and related resources are managed as a process or series of interconnected processes.

Improvement: We have committed to achieving continual improvement across all aspects of our quality management system; it is one of our main annual objectives.

Evidence-based decision making: As an organization we have committed to only make decisions relating to our QMS following an analysis of relevant data and information.

Relationship management: IMSM Ltd recognises that an organization and the relationship it has with its external providers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Our policy is also to meet the requirements of other interested parties and in meeting our social, environmental, charitable, regulatory and legislative responsibilities.

We have produced quality objectives which relate to this policy and they can be found in document R03 Quality Objectives.

This policy is available and communicated to all interested parties as well as being made available to the wider community through publication on our Website, Company Noticeboard and Intranet.

Authorized by: Ralph Karubian Position: Director

Date Approved:

M03 - Risk Assessment Procedure

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1. Introduction

Organizations have to balance risk versus reward in their decision making. An organization's risk management approach must be set within the context of the organization's business, the inherent risks and the organization's appetite for risk. A risk management process ensures that an organization manages its risk consistently by establishing a repeatable process and appropriately, by ensuring that the cost of mitigating (or reducing) the particular risk can be justified when considering the consequence of accepting the risk.

2. Purpose of Document

The purpose of this document is to provide a description of the risk management framework which sets the context for an organization's risk assessment methodology. Specifically, this document will cover:

- Risk management framework including the organization's business context, inherent risks, the organization's risk appetite, an established risk policy, responsibilities and authority, the need to assess risks at all levels within an organization's risk based decisions-making and the criteria for risk acceptance;

- Risk assessment procedure to ensure that the organization establishes repeatable assessments and continually improves its processes and procedures for the identification, analysis, evaluation, treatment and residual risk acceptance.

3. References

- ISO/IEC 31000 Risk Management – Principles & Guidelines

4. Executive Summary

Organizations face inherent risks of doing business, these risks can be internal or external, more often a combination of both. As part of good corporate governance, organizations are required to manage risks at all levels across their business. Organizations should give consideration to the potential for risks to affect the achievement of its strategic objectives and how risks can influence strategic decision making. From an operational perspective, the organization needs to give consideration to risks that have the potential to impact its operational performance and efficiency level, and from a project perspective, risks need to be managed to ensure that they do not affect the project outcomes and business case. Hence, all decision making within the organization should involve consideration of risk and should be assessed in a consistent and repeatable manner. The risk management approach must be an integrated part of the organization's governance for the risk management framework to be effective.

The ISO 31000:2009 Risk Management standard *"… recommends that organizations develop, implement and continuously improve a framework whose purpose is to integrate the process for managing risk into the organization's overall governance strategy and planning, management, reporting processes, policies, value and culture"*.

For risk management to be appropriate, it must be set within the context of the organization's business context, inherent risks, the organization's risk appetite, an established risk policy and well defined responsibilities and authority (i.e. risk management framework). In order for risk management to be effective, it must be consistent, repeatable, underpinned by well defined processes and procedures and continually improved (i.e. risk assessment processes and procedures).

5. Risk Management Framework

5.1 Risk Management Policy

The organization should have a risk management policy which is their statement of intent for managing risks; the policy would include high level statements covering the objectives of risk management, relationship between risk management and achievement of strategic intent, senior management commitment, performance measurement, reporting, continuous improvement, accountability and responsibilities and scope. The risk management policy will be communicated internally and as appropriate, externally to stakeholders, customers and suppliers.

5.2 Responsibility, Authority & Stakeholders

The executive management has ultimate responsibility for effective risk management across the organization. The executive management board will delegate authority throughout the organization but will also retain responsibility. The executive management will be required to endorse and demonstrate commitment to their risk management policy and monitor performance indicators for internal and external stakeholders as well as legal and regulatory compliance.

5.3 Integration

Risk management must operate at all levels within an organization in an integrated manner in order to be effective. Risk management should be considered at a strategic, operational and project level – and should take into account both internal and external factors (i.e. horizontally and vertically). Risk management processes and procedures must be an integrated part of the organization's business. Good corporate governance requires effective risk management down and across the organization.

5.4 Risk Evaluation Criteria

The organization should define the criteria to be used to evaluate the significance of risks; this should be defined so as to lead to consistent results and be subject to continuous review and improvement. A number of factors will influence the organizations criteria for evaluating risks (e.g. likelihood, consequence, nature of the impact, reputational damage, revenue impacting, external factors etc.).

5.5 Risk Acceptance

Organizations will often decide to accept risks based on due considerations such as the cost to mitigate is too high, the likelihood is low and the consequences are acceptable, the reward is worth the risk (risk versus reward) or cost of doing entering new markets.

5.6 Internal and External Factors

Organizations will need to carefully consider the interest of both internal and external factors in their risk management approach. Such factors include customers, suppliers, competitors, stakeholders, shareholders, their products and services, their employees, legislation and regulation. The organization will need to consider risks to and risk arising from various internal and external factors.

5.7 Continuous Improvement

Continuous improvement must be an integral part of the risk management approach. The executive management will typically set high-level targets and goals which will be owned by the operational functions / departments that will capture and report on metrics that contribute to the high level targets and goals. In order to identify and implement improvements, an organization must monitor and measure its achievement of performance targets.

5.8 Reporting & Communication

The organization is required to report and communicate internally and often externally on its risk management to demonstrate effective governance, to provide confidence that it is managing risks in accordance with its policy and for legal and regulatory compliance.

6. Risk Assessment Procedure

The Company performs a review of risks and undertakes risk assessments on a regular basis and when there is a significant change at strategic, operational or project level.

6.1 Risk Identification

During risk identification, the Company has considered all eventualities that could have an impact on the achievement of a stated objective or plan. At a strategic level, the Company has considered the events that would impact the achievement of its strategic intent (e.g. political uncertainty, competitors, labour market skills shortage, delays in product launch, becoming the target of a hostile acquisition, cyber security threats etc.) associated with the loss of confidentiality, integrity and availability for information within the scope of the management system. At an operational level, the Company has considered the events that would impact its achievement of production targets, quality sign-off, product launch, new IT system implementation or change programme. At project level, the Company has considered the events that would impact the achievement of planned initiatives.

During the risk identification stage, the Company has identified and documented a comprehensive list of risks; the Company has defined the most appropriate method to achieve this end. The organization has chosen the most appropriate method for identifying risks, although this may vary depending on whether risks are being identified at a strategic, operational or project level. The Company has chosen to identify risks against their assets and to hold risk management workshops with a multi-discipline representation. The Company has also identified the owner of any identified risk as part of this process.

However the Company decides to go about this process, the output from the risk identification will be a comprehensive set of risks, with associated impact(s), events (or cause) that could give rise to the risk and the consequence. The impact and consequence should be rated (e.g. high, medium, low) or quantified if possible to do so at this stage. The output from the risk identification stage is typically documented in a risk register.

6.2 Risk Analysis

The Company's approach for risk analysis is systematic and repeatable so that the relative significance and importance of risks can be assessed. The output from the risk identification stage forms the input to the risk analysis stage. The purpose of the risk analysis is to develop a qualitative and / or quantitative assessment of the risk so that the Company can judge the relative significance and priority of risks. During the risk analysis stage, the appropriate persons with the relevant subject matter, process knowledge and authority will be involved. The risk analysis stage involves gaining a more in-depth understanding of the characteristics of the risk,

in particular the impact, consequences, likelihood and relationships between risks (i.e. multiply effect). The output from this stage is a risk assessment, whereby risks are scored based on an analysis of their impact, consequence and likelihood.

6.3 Risk Evaluation

The output from the risk analysis forms the input to the risk evaluation stage. The purpose of the risk evaluation is to consider risks within the context of the Company's risk appetite and risk evaluation criteria which are defined as part of the risk management framework. The Company will make decisions about whether or not to treat and the priority for treatment of risks. The responsible and or authorised persons will be involved in the risk evaluation decision making.

6.4 Risk Treatment

The organization's decision on risk treatment should be based on risks versus reward and the business case benefits should also be considered. The output from the risk evaluation provides input to the risk treatment considerations. Depending on the type of risk and its significance to the business, the decision makers may choose to:

- **Avoid** – the Company may choose not to implement certain activities or processes that would incur the risk (i.e. eliminate the risk by eliminating the potential cause);
- **Mitigate** – to reduce the likelihood or impact of the risks by implementing appropriate mitigating controls;
- **Transfer** – to share the risk with a partner or transfer via insurance coverage, contractual agreement or other means;
- **Accept** – formally acknowledge and sign-off acceptance of the risks

6.5 Residual Risk

Even after risk treatment, is mitigated or transferred there may still exist a degree of risk which is known as the residual risk. Decision makers should ensure that they understand the extent of the residual risks remaining after treatment and this should be documented, accepted, monitored and reviewed on a regular basis.

6.6 Monitoring and Review

As an integral part of the risk management process, the Company will regularly review, monitor, report and communicate internally and as appropriately externally on the outcomes and effectiveness of the risk management process.

6.7 Continuous Improvement

The Company will identify opportunities for improvement, so that the risk assessment outcomes continue to be appropriate, relevant and effective.

7. Related Documentation

R02 Risk Assessment Register

M04 - Planning to achieve Quality Objectives

1 Introduction

The Organization has established a number of Quality Objectives for the coming year, details of which can be found in document: **R03 Quality Objectives**.

This document details, amongst other things, the process we have gone through when establishing these objectives, how they will be monitored and how to evaluate results.

2 Process to Establish

2.1 A quality objective shall be consistent with our Quality Policy (**M02 Quality Policy**) and will relate in whole or in part to our Organization or a particular department; details of how the objective will be measured will also be documented in **R03 Quality Objectives** as each measure may be specific rather than generic to the objective.

2.2 The objective will take into account all applicable requirements, will be relevant to the conformity of the products and services we produce and will look to enhance customer satisfaction.

2.3 Each objective will be monitored by our Quality Representative at regular intervals with reports given to Top Management on the results of the monitoring process.

2.4 Information on each objective will be communicated throughout our Organization together with any available results. A final assessment will be communicated following the relevant Management Review meeting.

2.5 Where it is deemed appropriate we will update an objective or its desired results to ensure that it remains relevant and effective to our requirements.

2.6 Each objective will be measureable and detail the following information:

- What will be done
- What resources will be required to achieve our desired result
- Who will be responsible for ensuring our desired results are achieved
- When the objective has to be achieved
- How we plan to evaluate the results

2.7 Results on how we performed will be discussed at our Management Review meeting.

3 Related Documentation

R03 Quality Objectives

M05 - Monitoring & Measuring Resources

We have looked at the requirements of this clause in the standard and have determined that they are not applicable to the scope of our management system.

M06 - Document Control & Records

1 Introduction

To demonstrate that the company's stated quality objectives have been satisfied, a detailed system of control for quality related documentation and records needs to be maintained.

2 Scope

The Company will produce and maintain adequate documentation to detail the requirements of the quality management system and to ensure that the requirements of the customer can be satisfied. Adequate records must be maintained for this purpose.

This procedure also applies to all records generated under the other procedures in the quality management system.

3 Responsibility

It is the responsibility of Top Management to ensure that:

a. The Quality Management System is adequately documented.

b. Documents are properly controlled and approved and are readily available to those personnel that need to use them.

c. Sufficient records (electronic or hardcopy) are maintained and these are legible and readily found.

4 Procedure

4.1 Document and Data Control

4.1.1 All quality manual documentation must carry a unique identification number, an issue number and the date from which the document becomes effective.

4.1.2 Documents must be formally approved for use.

4.1.3 Other quality documents must be clearly identified by their title or other reference, traceable from the document master register.

4.1.4 A master documents register held in QMS Manual Q05 will be available and will carry the current issue of each controlled document copies of which may be held elsewhere as their day to day use requires.

4.1.5 Obsolete documents will generally be withdrawn from the system. If obsolete documents are retained the reasons why must be noted on the master documents register

4.1.6 External documentation must be adequately controlled to ensure that it is not damaged or lost.

4.1.7 All forms must be periodically assessed under the Quality Audit procedures for currency and fitness for use.

4.1.8 Any changes required to documentation must follow the process documented above; they must be approved by Top Management prior to use.

4.1.9 Access to documentation will be allocated on a case by case basis.

4.2 Records

4.2.1 All completed quality documentation and records must be retained for at least three years unless specified in other regulations or by legislation. Other documentation should be retained in line with agreed legislative and regulatory requirements.

4.2.2 Records must be correctly filed under suitable headings, in files, folders etc. so that they can be readily found. Adequate security must be maintained to ensure that records are not lost or damaged.

4.2.3 Records must be legible.

4.2.4 Records kept on computer or on other electronic media must be backed up on a regular basis such that the information can be recovered if necessary.

4.2.5 Records may be destroyed at the end of their retention period.

4.3 Backups of Computer Systems

4.3.1 Where the Company's operations are electronically held and processed it is essential that protection be provided against the loss or corruption of data or work in progress.

4.3.2 The computer system will have a backup taken at least daily and at interim intervals as determined by Senior Management. Each backup will contain all the data that may have changed during the intervening period.

4.3.3 Backups will be carried out as a stand-alone process with no other users logged on at the time. Senior Management will assign the backup task as required.

4.3.4 Additional backups will be done on a regular basis and stored off site.

4.3.5 At intervals, determined by Senior Management, a trial "restore" from the latest set of backup media will be carried out onto a separate machine or environment / partition.

4.3.6 At regular intervals, Senior Management will ensure the virus protection software on the Company’s computer systems is updated and the files scanned.

5 Related Documentation

QMS Manual Q05 Document Register

M07- Design & Development

We have looked at the requirements of this clause in the standard and have determined that they are not applicable to the scope of our management system.

M08 - Control of External Providers

1 Introduction

It is essential that the work carried out on behalf of the organization is adequately controlled to ensure that it meets the requirements of the customer. This is achieved by good planning, the provision of adequate resources, properly trained and experienced personnel, clearly defined standards and methods of working and correct monitoring and product verification.

2 Scope

The scope of this procedure includes requirements for the control of externally provided products and services when:

a. Products and services are provided by external providers for incorporation into our own products and services,

b. Products and services are provided directly by the external provider to our customer,

c. A process or part process is provided by an external provider following our decision to outsource.

3 Responsibility

It is the responsibility of Top Management to ensure that external providers:

a. Adequately define and control all work they carry out for the organisation.

b. Provide adequate instructions to their personnel to ensure that the quality of work is satisfactory and these are readily available.

c. Have defined standards of workmanship and criteria for acceptance.

d. Ensure that suitable personnel are assigned for the work process and for product verification and checking activities.

e. Ensure that adequate resources are provided in the form of personnel, equipment and a suitable working environment.

It is the responsibility of all personnel to comply with this procedure and seek guidance from management where clarification is required.

4 Procedure

General

We have established set criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide the required products and services.

The criteria are as follows:

- Product Quality
- Rejections
- On-tine Delivery
- Delivery Errors
- Expense
- Customer Service
- Environmental

Type and extent of control

When considering the controls required we have taken into account the following:

a. The potential impact of externally provided processes, products and services to meet customer, statutory and regulatory requirements

b. The effectiveness of the controls applied to the external provider and the resultant output

We have established and implemented verification activities which are applied to external providers to ensure we continue to meet customer, statutory and regulatory requirements. The performance of external suppliers shall be formally reviewed through Management Review (see M13) with the External Providers Evaluation Results (see R12) being updated accordingly.

Information for external providers

We communicate with our external providers the applicable requirements of providing products and services to our organization. The information communicated will include information on the following:

a. The processes, products and services to be provided or performed

b. The approval products, services, methods, processes, equipment and the release of products and services

c. The required competence of personnel

d. The interactions with our QMS

e. The control and monitoring of external providers performance

f. The verification activities that we intend to perform at the external providers premises

5 Related Documentation

R12 External Providers Evaluation Results

M09 Production & Service Provision

1 Introduction

It is essential that the work carried out by the organization is adequately controlled to ensure that it meets the requirements of the customer. This is achieved by good planning, the provision of adequate resources, properly trained and experienced personnel, clearly defined standards and methods of working and correct monitoring and product verification.

2 Scope

The scope of this procedure includes:

a. Control of the work process.

b. Validation, identification and traceability of the work.

c. Customer and others property.

d. Control of associated activities including handling, packing, storage, preservation and delivery and post-delivery activities if applicable.

e. Control of changes and release of Products and Services

3 Responsibility

It is the responsibility of Top Management to ensure that:

a. All work carried out by the organization is adequately defined and controlled.

b. Appropriate instructions are provided and maintained to ensure that the quality of work is satisfactory and these are readily available.

c. Standards of workmanship and criteria for acceptance are defined.

d. Suitable personnel are assigned for the work process and for product verification and checking activities.

e. Adequate resources are provided in the form of personnel, equipment and a suitable working environment.

It is the responsibility of all personnel to comply with this procedure and seek guidance from their Managers where clarification is required.

4 Procedure

Control of production and service provision

All work carried out by our organization will be carried out under controlled conditions which shall include, where applicable, the availability of documented information defining the characteristics of the product and service, the activities to be performed, the results to be achieved, the use of suitable infrastructures and the monitoring, measurement, verification and validation activities necessary, the competence and qualification of personnel and the implementation, release, delivery and post-delivery activities necessary.

Work instructions are given through the use of customer orders and specifications and activities are documented with the use of Picking Slip, Delivery Dockets, Warranty Repair Forms, Items for Stock Forms and Bastardised Stock Forms.

We will also take into account any applicable Health and Safety requirements and statutory legislation. Good standards of housekeeping will be maintained at all times.

All records associated with the work process are kept in accordance with M06 Document Control and Records.

All personnel carrying out work will be suitably trained and experienced in accordance with organizational requirements. We will implement actions to prevent human error.

Identification and traceability

Products, and their status with respect to measuring and monitoring, are identified throughout the provision process. Where traceability is a requirement we control the unique identity of the product and retain the relevant documentation. We identify our products to enable identification and traceability.

Property belonging to customers and external providers are identified as such when applicable.

We identify, verify, protect and safeguard property belonging to our customers or external providers.

When such property is lost, damaged or otherwise found to be unsuitable documentation will be retained regarding the report to the customer or provider.

Preservation

We preserve our products to maintain conformity of requirements.

Post-delivery activities

We have determined the post-delivery activities associated with our products and services; in doing so we have looked at the customer requirements, potential undesired consequences, nature, use and lifetime of the product and service, customer feedback and statutory and regulatory requirements.

The post-delivery activities are, where necessary, produced for each product and service type.

4.1 Control of changes

We review and control changes necessary for the production and service provision to ensure continued conformity of our products and services. The controls necessary are in the form of written instruction from the client.

We keep documented records of any such changes, including the review of the change, the person who authorized the change and any resultant actions using form R14 – Document Change Request.

Release of products and services

We have implemented arrangements for the release of our products and services in accordance with customer requirements.

5 Related Documentation

R07 Conformity Documentation
R08 Operational Planning
R14 Document Change Request

M10 Control of Nonconforming Product

1 Introduction

In the event of defective or substandard work being produced or a non-conformance occurring, the Non-Conforming product or service etc. needs to be identified and corrected to prevent potential customer complaints or continued nonconformity. The causes need to be reviewed over time to prevent recurrence, if possible.

2 Scope

This procedure addresses non-conformance, including to products and services at all stages in the organization's work process.

3 Responsibility

It is the responsibility of the following personnel to ensure that non-conformances are identified and corrected, the root causes are addressed and the necessary records are maintained.

a.	Customer Complaints.	Quality Representative
b.	Product/Service Non-Conformances.	Quality Representative
c.	Quality System Non-Conformances.	Quality Representative

4 Procedures

Non-conforming Products & Services

4.1 Routine verification and monitoring at all stages in the work process should be aimed at identifying any Non-Conforming or defective products or services. All personnel must report Non-Conformances.

All identified Non-Conforming products/services are segregated to prevent inadvertent use.

All Non-Conforming services must be dealt with promptly to prevent the deficiency becoming worse or affecting the customer.

The Non-Conformance will be corrected by the most appropriate and cost effective method.

Non-Conformances must be recorded together with the action taken to correct them. They must be reviewed to allow identification of the root causes and trends.

Where concessions are required from the customer, regulatory body or other organizations, this will be recorded.

Nonconformity & Corrective Action

When non-conformity occurs, including those arising from customer complaints we will take the following steps:

4.1.1 React to the non-conformity (NC) and take action to control and contain the immediate situation and correct the situation and deal with the consequences.

4.1.2 Evaluate the need for action to eliminate the causes of the NC in order that it doesn't recur or occur elsewhere by reviewing the NC, determining the causes of the NC and determine if similar NCs exist elsewhere.

4.1.3 Implement any corrective actions required

4.1.4 Review the effectiveness of any corrective actions taken

4.1.5 Update risks and opportunities determined during planning, if necessary

4.1.6 Make any necessary changes to the quality management system

4.2 Corrective actions will be appropriate to the effects of the non-conformity that occurs. However it may be impossible to completely eliminate the causes of the NC although corrective actions may reduce the likelihood of reoccurrence.

4.3 Details of each reported non-conformity is recorded using the appropriate document. This document allows for the recording of the NC as well as appropriate corrective actions.

4.4 These documents are retained for future reference purposes and for use at Management Review meetings.

5 Related Documentation

R19 Non-conformance Report Form
R20 Corrective Action Report Form

M11 Monitoring & Measurement Results

1 Introduction

The Organization has determined what needs to be monitored and measured; the methods for monitoring, measurement, analysis and evaluation; when the monitoring and measuring shall take place and when the results will be analysed. Details of which can be found in section 2 of this document.

2 Criteria

2.1 We will monitor and measure the following:

- Customer satisfaction
- Product/Service conformity
- Delivery Performance
- Corrective Actions
- Audit findings
- Performance of external providers

2.2 The methods that will be adopted will be as follows:

- Customer satisfaction - Client Feedback
- Product/Service conformity – Nonconformity Reports
- Delivery Performance – Nonconformity Reports
- Corrective Actions – Corrective Action Reports
- Audit findings – Internal Audit Reports
- Performance of external providers – Supplier Performance Reviews

2.3 The task will be performed at these times:

- Customer satisfaction – on-going
- Product/Service conformity – on-going
- Delivery Performance – on-going
- Corrective Actions – on-going
- Audit findings – As per Audit programme
- Performance of external providers - Annually

We will analyse and evaluate the results from these and other sources. The output of this analysis shall be used to evaluate conformity of our products and services, the degree of customer satisfaction, assess the performance and effectiveness of our QMS, if planning has been implemented effectively, the effectiveness of actions to address risk and opportunities, performance of external providers and the need for improvement to the QMS.

The results of this analysis and evaluation will be reviewed as part of our Management Review meeting.

3 Related Documentation

R18 Management Review Agenda and Minutes

M12 Internal Audit

1 Introduction

The organization's Quality Management System needs to be audited on a systematic basis to ensure that the planned arrangements are being met in practice and that it continues to meet applicable requirements of ISO 9001.

2 Scope

This procedure details the method of planning and carrying out the internal audit to check that the organization's procedures are being followed.

3 Responsibility

It is the responsibility of Top Management to ensure that:

a. An internal audit programme is prepared to cover all elements of the Quality Management System.

b. Suitable personnel are allocated to carry out the internal audits.

It is the responsibility of the Internal Auditor to carry out the audits, identify any Non-Conformances and follow them up to ensure that they are corrected.

4 Procedure

Planning

4.1.1 An internal audit programme must be prepared covering all elements of the Quality Management System. The programme will be structured in such a manner as to ensure each procedure is audited at least annually.

4.1.2 Suitably trained auditors must be assigned to carry out the audit of each element of the system. Note that the auditor should be independent of the work or area being audited.

4.1.3 Additional audits may be scheduled where problems or deficiencies have been found.

Conducting the Audit

4.1.4 The Internal Auditor(s) will carry out the audits in accordance with the programme.

4.1.5 Using the procedure itself as the guide, each element will be checked to ensure that its requirements are being met and that the overall purpose of the procedure is being fulfilled.

4.1.6 Written notes on variances, Non-Conformance and omissions will be taken and circulated for action to appropriate personnel.

4.1.7 Supplementary notes will be taken of supporting information and records checked, e.g. job numbers, purchase orders.

Reporting and Closing Out Non-Conformances

4.1.8 The Internal Auditor will be responsible for following up designated actions and for the making of information on incomplete items available to the Management Review Meeting.

4.1.9 If the Internal Auditor believes that any procedure or method of working is not meeting its intended objectives, could be improved or that further information is required, it will be discussed with the appropriate manager and Corrective Action taken. This will be reported to the Management Review Meeting.

5 Related Documentation

R16 Internal Audit Programme
R17 Internal Audit Report
R19 Non-conformance Report Form

M13 Management Review

1 Introduction

The Quality Management System needs periodic reviews to ensure that it meets the requirements in respect of continued suitability:

a. Policy and Objectives

b. Adequacy and Effectiveness

c. Opportunities for Improvement

All changes to the Quality Management System / policy / and objectives are kept up to date.

2 Scope

The Management Review must cover the operation of the Quality Management System throughout the Organization.

3 Responsibility

It is the responsibility of Top Management to ensure that:

a. The Quality Management System is reviewed at planned intervals to ensure its continued suitability, adequacy and effectiveness.

b. The minutes of the meeting are recorded.

c. Any actions are identified and corrected.

d. Opportunities for improvement are identified and implemented.

4 Procedure

4.1 The Management Review must be held at planned intervals as agreed with top management to address all parts of the Organization's Quality Management System:

a. To determine whether the company is operating effectively to the benefit of the Organization.

b. To identify opportunities for improvement.

c. To determine whether the Organization is continuing to meet customer requirements.

d. To prevent Non-Conformity.

The meeting must be attended by the Quality Representative, representatives of top management and other staff as appropriate. The meeting shall address the following topics:

- Actions from previous management reviews
- Changes in external/internal issues relevant to the QMS
- Information on quality performance, including trends (analysis and evaluation – see QMS clause 9.1.3) for:
  - Nonconformities and corrective actions
  - Monitoring and measurement results
  - Audit results
  - Customer satisfaction
  - Meeting quality objectives
  - Issues concerning interested parties and external providers
  - Process performance and conformity of products and services
- Effectiveness of actions to address risk and opportunity
- Adequacy of resources
- Opportunities for improvement

4.2 The review must cover as a minimum the period since the last Management Review Meeting.

4.3 The person responsible for any actions identified at the meeting must be recorded together with target dates for completion where appropriate. The Organization must allocate the necessary personnel and resources for these corrective actions.

4.4 Outputs from the Management Review shall include decisions related to:

a. Improvement opportunities
b. Changes to the QMS
c. Additional resource requirements.

4.5 The minutes of the meeting must be recorded and retained for future reference. Copies must be provided to all personnel who attended the meeting together with those who have actions placed upon them.

5 Related Documentation

R18 Management Review Agenda & Minutes